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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,615	06/27/2001	Ian Duncan Rubin	013306-5003	8850

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EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	7

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/891,615	Applicant(s) RUBIN ET AL.	
	Examiner Patrick T. Lewis	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 18, 25, 29-30, 32, and 34, drawn to a method of treating or preventing diabetes by administering to a human or animal an effective dosage of an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*, classified in class 514, subclass 54.

II. Claims 13-15, 23, 31, and 33, drawn to an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*, classified in class 536, subclass 123.1.

III. Claims 16-18, 21, 25, 27, 29-30, 32, and 34, drawn to a method of treating or preventing diabetes comprising administering to a human or animal an effective dosage of at least one compound of general formula (A), classified in class 514, subclass 54.

IV. Claims 19-20, 22-24, 31, and 33, drawn to a compound of general formula (A), classified in class 536, subclass 123.1.

V. Claims 26 and 29-30, drawn to a method of decreasing blood glucose level comprising administering to a human or animal an effective dosage of an effective dosage of an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia* or at least one compound of formula (A), (1), (2), (3),

(4), (5), (6), (7), (8), (9), (10), (11), (12), (13), or (14), classified in class 514, subclass 54.

VI. Claims 28-30, drawn to a method of treating impaired glucose tolerance comprising the step of administering to a human or animal an effective dosage of an effective dosage of an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia* or at least one compound of formula (A), (1), (2), (3), (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), or (14), classified in class 514, subclass 54.

2. Inventions (I and II) and (I and IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of invention II or IV may be used to practice the method of Invention V.

3. Inventions (I and III), (I and V), and (I and VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions I and III are unrelated because different active agents are employed in the methodological steps. Inventions V and VI differ from Invention I because Inventions V and VI are drawn to methods for affecting different conditions.

4. Inventions (II and III) and (II and IV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions II and III are unrelated because the method of Invention III employs an active agent distinct from Invention II. Inventions II and IV are unrelated because the compounds of Invention IV do not have to be present in the extract of Invention II.

5. Inventions (II and V) and (II and VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of invention V or VI may be practiced using compounds of invention IV.

6. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds of invention IV may be employed in the methods of Inventions V or VI.

7. Inventions (III and V) and (III and VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

MPEP § 808.01). Inventions II and III are unrelated because the method of Invention III employs an active agent distinct from Invention II. Inventions V and VI differ from Invention III because Inventions V and VI are drawn to methods for affecting different conditions.

8. Inventions (IV and V) and (IV and VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of invention V or VI may be practiced using extract of Invention II.

9. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions VI are drawn to methods for affecting different conditions.

10. Claims 23, 31, and 33 link(s) inventions II and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 23, 31, and 33. Claims 25, 32, and 34 link(s) inventions I and III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 25, 32, and 34. Claims 29-30 link(s) inventions I, III, V, and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 29-30. Upon the allowance of the linking claim(s), the

restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

11. In the event applicant elects the invention of Group III, IV, V, or VI, applicant is required to elect a species in accordance with the provisions set forth below:

Claims 16-17 generic to a plurality of disclosed patentably distinct species wherein:

$\mathbf{R_2}$ is species **A** (H) or species **B** (one or more 6-deoxy carbohydrates, one or more 2,6-dideoxy carbohydrates, glucose, or combinations thereof);

$\mathbf{R_3}$ is species **C** (H, alkyl, or acyl) or species **D** (glucoxy);

$\mathbf{R_6}$,$\mathbf{R_7}$ is species **E** (carbonyl) or **F** ($\mathbf{R_6}$ = H and $\mathbf{R_7}$ = O$\mathbf{R_3}$).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623

Johann Richter, PhD, Esq.
Supervisory Patent Examiner
Technology Center 1600

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August 17, 2002